FILE COPY

No. 654

Supreme Court, U.S.
FILED
JAN 22 1960
JAMES R. BROWNING, Clerk

Supreme Court of the United States

OCTOBER TERM, 1959

DYESPECIES & CHEMICALS, INC., *Petitioner*,

v.

ARTHUR S. FLEMMING, Secretary of Health, Education and Welfare, *Respondent*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PAUL C. WARNKE,
ROBERT L. RANDALL,
701 Union Trust Building,
Washington 5, D. C.

EARL SUSMAN,
705 Olive Street,
St. Louis 1, Missouri

Attorneys for Petitioner

COVINGTON & BURLING,
701 Union Trust Building,
Washington 5, D. C.

SUSMAN, MAYER & WILLER,
705 Olive Street,
St. Louis 1, Missouri

Of Counsel

INDEX

	Page
Opinions Below	1
Jurisdiction	2
Question Presented	2
Statutes Involved	2
Statement	3
Reasons for Granting the Writ	7
Conclusion	11

CITATIONS

Cases:

Denver Union Stock Yard Co. v. Producers Livestock Marketing Association, 356 U.S. 282	7
Flemming v. Florida Citrus Exchange, 358 U.S. 153	4, 6, 7, 8, 9, 10
United States v. Storer Broadcasting Company, 351 U.S. 192	7

Statutes:

21 U.S.C. § 371	2, 3, 4
21 U.S.C. § 346	2, 3, 4
28 U.S.C. § 1254(1)	2

Miscellaneous:

22 Fed Reg. 478	5
22 Fed. Reg. 3173	5, 6
22 Fed. Reg. 6613	6
24 Fed. Reg. 883	2, 4, 6
25 Fed. Reg. 142	10

Supreme Court of the United States

OCTOBER TERM, 1959

No.

DYESTUFFS & CHEMICALS, INC., *Petitioner*,

v.

ARTHUR S. FLEMMING, Secretary of Health, Education and Welfare, *Respondent*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

Petitioner prays that a writ of certiorari issue to review the judgment of the Court of Appeals for the Eighth Circuit rendered on October 30, 1959, (Appendix p. 14a). This judgment affirmed the order promulgated by respondent on February 6, 1959, (R. 1).

OPINIONS BELOW

The opinion of the Court of Appeals, which is reported at 271 F.2d 281, is printed as an Appendix to this petition.

The order of respondent is reported at 24 Fed. Reg. 883 and appears in the record at page 47.

JURISDICTION

The judgment of the Court of Appeals for the Eighth Circuit was entered on October 30, 1959. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTION PRESENTED

The Congress has provided in 21 U.S.C. §§ 371(e)(2) and (3) that prior to amendment of the food color certification regulations, persons adversely affected "may file objections thereto with the Secretary" and request a public hearing upon such objections after which the Secretary

> "shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections."

The following question is presented:

May the Secretary amend the food color certification regulations without holding a public hearing because prior objections, which were filed with respect to a prior proposed amendment, raised issues that are no longer deemed relevant, or must persons adversely affected be given the opportunity to file objections and have a public hearing based on issues of fact and law which are relevant to the amendment as announced?

STATUTES INVOLVED

Section 406(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 346(b)) provides that

> "The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents."

Sections 701(e)(2) and (3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 371(e)(2) and (3)) provide that

> "(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor and requesting a public hearing upon such objections.
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions."

STATEMENT

Petitioner is and for forty years has been a producer of food colors, two of which, known as FD&C Yellows 3 and 4, are used to color edible fat products such as

butter and oleomargarine. Until the administrative action that forms the basis for this petition, these two colors had been certified as safe for use as food colors by respondent pursuant to the provisions of the Federal Food, Drug and Cosmetic Act (hereafter the Food and Drug Act). On February 6, 1959, respondent, without notice or hearing, promulgated an Order (24 Fed. Reg. 883) which purported to amend the regulations under § 406(b) of the Food and Drug Act so as to exclude the two colors in question and thus prevent their certification for use as food colors.

Judicial review of this Order was sought by petitioner in the court below pursuant to the provisions of § 701(f) of the Food and Drug Act. In its petition for judicial review, petitioner questioned the validity of respondent's action on the ground that it had been taken without affording petitioner the right to file relevant objections thereto and without a public hearing both of which are required by the provisions of the Food and Drug Act. Petitioner requested the court below to direct respondent to consider the objections that petitioner and others adversely affected were entitled and prepared to make so that there might be a record of relevant evidence on which respondent's action might be properly reviewed. The court below sustained respondent's Order and denied the requested relief on the ground that petitioner's prior objections, which were filed to an earlier Order proposed in 1957, were no longer relevant because they did not meet the subsequent test laid down by this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, which formed the basis of respondent's Order of February 6, 1959. It thus held that, as the only objections that had been filed were to be regarded

as a nullity, respondent was not required to hold a public hearing to consider them.

The context of this curious holding below is as follows:

On January 24, 1957, respondent first proposed the exclusion of the two colors here in question from the list of certified colors and invited interested persons to submit comments within thirty days (22 Fed. Reg. 478) (R. 1).

On May 4, 1957, respondent published the text of an order providing for the delisting of the two food colors. The order, which by its terms was to become effective ninety days thereafter, stated that objections and requests for a public hearing should be submitted by persons adversely affected within thirty days (22 Fed. Reg. 3173) (R. 40). Petitioner, among others, filed timely objections to the order which were predicated upon what was then thought to be the correct construction of the statutory test contained in § 406(b) of the Food and Drug Act. That is, the factual issues raised by petitioner's objections as filed concerned the question of whether the food colors in question were harmless if used as intended. On August 17, 1957, the proceeding was stayed in its entirety by the promulgation of an order which in pertinent part stated:

> "Within the time allowed, objections were received [to the order of May 4, 1957] from firms asserting that the order if placed into effect would adversely affect them, specifying objections, stating grounds therefor, and requesting a public hearing. The objections filed protested each of the provisions of the above-referenced amending order.

> Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 701(e); 52 Stat. 1055; 70 Stat. 919; 21 U.S.C. 371(e)) and to the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education and Welfare (22 F.R. 1045): *It is ordered*, That the amendments to the regulations for color certification made in the order published in the Federal Register of May 4, 1957 (22 F.R. 3173), are stayed in their entirety.
>
> In accordance with the provisions of section 701 of the Federal Food, Drug, and Cosmetic Act, the Commissioner of Food and Drugs will subsequently announce a hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections filed to the order." (22 Fed. Reg. 6613) (R. 46).

No hearing was announced, however, and the proceeding was continued in a pending status. Then, on December 15, 1958, this Court handed down its opinion in *Flemming* v. *Florida Citrus Exchange*, *supra*. There it was determined that the relevant factual question was whether a food color was capable of causing harm in laboratory animals when fed at "toxicologically significant" levels, even though these levels were many times those present under conditions of actual use in food. Hence, the only factual issue which petitioner had considered or contested in its 1957 objections became irrelevant. Without affording petitioner an opportunity to submit objections and evidence, based on the new criterion, respondent promulgated the Order here in question, on February 6, 1959 (24 Fed. Reg. 883) (R. 1). That Order noted that although a public hearing had been requested when the earlier Order had been proposed, "no purpose could be served by holding

a public hearing" because the earlier objections had sought to raise the wrong factual issue and thus were now "without substance."

REASONS FOR GRANTING THE WRIT

The Court of Appeals, on the basis of what all concede to be an irrelevant record, albeit the only possible record in the circumstances, has erroneously decided an important question of Federal law in a way which conflicts with a decision of this Court.

The court below rested its decision on the conclusion that petitioner's four stated "grounds for objections" to the Order of May 4, 1957, "were insufficient to warrant a hearing" on the Order of February 6, 1959. In other words, the pre *Florida Citrus* objections filed by petitioner were no longer "relevant and material to the issues" which formed the basis of the Order promulgated after that decision. The court below, having so phrased the question could only conclude that no hearing was warranted under *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Ass'n*, 356 U.S. 282, and *United States* v. *Storer Broadcasting Company*, 351 U.S. 192. The answer one receives depends on the way the question is asked. Thus, if the 1957 objections are viewed as being filed to the 1959 Order, these cases may be said to hold that, despite the statutory requirement that a hearing be held, no hearing is needed to consider complaints or objections which "do not state a valid basis for a hearing." However, neither *Denver Union Stock Yard* nor *Storer* is support for the unthinkable proposition that petitioner's right to be heard on the 1959 Order is to be judged on the basis of the dated learning contained in its May 27, 1957, objections.

Petitioner did not know until December 15, 1958, the day the *Florida Citrus* opinion was handed down, that its prior objections did "not state a valid basis for a hearing." After that date, respondent's actions were so paced that no opportunity was afforded for new and pertinent objections. The new Order was simply promulgated on February 6, 1959, and petitioner was told that its prior objections were insufficient. Indeed, they could not have been otherwise but for a clairvoyant anticipation by petitioner in early 1957 of the opinion in *Florida Citrus*. There is nothing in that opinion which condones such a result. In fact, the opinion assumes that the new test will be applied in regulations subject to the notice and hearing requirements of the Act.

In *Florida Citrus*, the Court held that the relative factual test for certification, whether a color, as used, "was harmful for human consumption," had been properly supplanted by the factual requirement that the colors in question be "wholly innocuous and demonstrated to be without adverse physiological effect."

> "This rule of caution is here one which relieves the Secretary from the burden of showing in each case that a food containing them raises a possibility of injury to health, and requires that the color stuffs, whose positive values are only visual and which are not naturally found in foods, not be added unless they could pass a higher standard." 358 U.S. at 162.

This Court's approval of the new rule settled the question of the showing required of the Secretary at the public hearing provided by the statute. It did not, as the court below assumed, vest in respondent that uncontrolled discretion to decertify a color with-

out a hearing which he exercised by his Order of February 6, 1959. The opinion of this Court in *Florida Citrus*, though it approves as the test for certifiability of coal-tar colors the harmlessness of the color itself, recognizes expressly that the Secretary's determination must be based on appropriate laboratory tests adduced at the public hearing required by the statute. Before delisting any coal-tar color, the Secretary must establish that the color is not "harmless" when administered "at toxicologically significant levels." 358 U.S. at 163. What petitioner sought below and what it asks here is no more than its statutory right to test, under the provisions of the Act at the public hearing contemplated by the Act, the toxicological data on which respondent purports to have relied in promulgating his Order of February 6, 1959.

Because of respondent's refusal to hold a public hearing, there is, of course, no "substantial evidence of record" to support the Order here in question. The Court below condoned respondent's arbitrary assumption that, because he had unilaterally concluded that the two food colors in question are "not harmless", public hearings could serve no purpose. This bald misapplication of *Florida Citrus* is strikingly revealed by a subsequent order of respondent, dated January 8, 1960, purporting to withdraw the certification of previously certificated batches of coal-tar colors, including FD&C Yellows No. 3 and 4. In the Order issued earlier this month, respondent recites:

> "Dyestuffs and Chemicals, Inc., filed objections requesting a hearing on the completeness, adequacy, and accuracy of the factual basis for the Department's action in removing FDC Yellows No. 3 and 4 from the approved list. Since the

> order decertifying these colors has been reviewed by the Court of Appeals for the Eighth Circuit and the Department's order has been affirmed, such regulations may not be challenged anew in this proceeding. Such objections are without legal validity and do not call for a public hearing." (25 Fed. Reg. 142).

Hence the decision of this Court in *Florida Citrus* —establishing the standard for certifiability of coal-tar colors as harmlessness when "administered at toxicologically significant levels"—has been distorted by the court below to foreclose petitioner's statutory right to test at a public hearing the evidentiary basis for respondent's conclusions. But the newly approved standard, or any other standard, is wholly meaningless until and unless it is put into the proper factual context by means of administrative proceedings. Without such proceedings the standard will mean only what respondent says it means. All objections may be disregarded as immaterial. And, of course, there will be nothing to review judicially. Such a result both vitiates the statutory command and, in fact, squarely conflicts with the *Florida Citrus* decision of this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

PAUL C. WARNKE,
ROBERT L. RANDALL,
701 Union Trust Building,
Washington 5, D. C.

EARL SUSMAN,
705 Olive Street,
St. Louis 1, Missouri

Attorneys for Petitioner

COVINGTON & BURLING,
701 Union Trust Building,
Washington 5, D. C.

SUSMAN, MAYER & WILLER,
705 Olive Street,
St. Louis 1, Missouri

Of Counsel

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 16,225

DYESTUFFS AND CHEMICALS, INC., *Petitioner*,

v.

ARTHUR S. FLEMMING, Secretary of Health, Education, and Welfare, *Respondent*.

Petition for Judicial Review of an Order Under the Federal Food, Drug, and Cosmetic Act

[October 30, 1959]

Earl Susman and Paul C. Warnke (Susman, Mayer & Willer and Covington & Burling were with them on the brief) for Petitioner.

William W. Goodrich, Assistant General Counsel, Department of Health, Education, and Welfare (Malcolm R. Wilkey, Assistant Attorney General, Robert S. Erdahl and Harold P. Shapiro, Attorneys, Department of Justice, and Robert H. Becker, Attorney, Department of Health, Education, and Welfare, were with him on the brief) for Respondent.

Before GARDNER, VOGEL and VAN OOSTERHOUT, Circuit Judges.

VOGEL, Circuit Judge.

Petitioner, Dyestuffs and Chemicals, Inc., herein seeks judicial review of an order promulgated by the respondent, Secretary of Health, Education, and Welfare, 24 F.R. 883, entitled "In the matter of amending the color-certification regulations with respect to FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4." Jurisdiction of this court to review the order complained of is based upon 21 U.S.C.A. § 317 (f) (1).

21 U.S.C.A. § 346 (b) (§ 406 (b) of the Federal Food, Drug and Cosmetic Act) provides that:

> "(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmful diluents."

Petitioner is a producer of food colors, including certain coal tar colors known as FD&C Yellows 3 and 4 which have been widely used in the coloring of edible fat products, principally butter and oleomargarine. FD&C Yellows 3 and 4 have been certified by the respondent and his predecessors under § 346 (b) as safe for such use for approximately the past 40 years. On January 24, 1957, the Deputy Commissioner of Food and Drugs published in the Federal Register, 22 F.R. 478, a notice of his proposal to amend the Food and Drug Administration regulations by removing FD&C Yellow Nos. 1, 2, 3 and 4 from the approved list for unrestricted use. This notice solicited the views and comments of interested parties. After receiving comments, including those of the Certified Color Industry Committee of which petitioner is a member, the Commissioner on May 4, 1957, published an order removing the colors in question from the approved list, 22 F.R. 3173, because they "are not harmless and suitable for use within the meaning of" 21 U.S.C.A. § 346 (b). Such order was to become effective 90 days after publication unless stayed by the filing of proper objections. On May 27, 1957, within the time provided by law, the Certified Color Industry Committee filed objections to the order and requested a hearing thereon in accordance with the provisions of 21 U.S.C.A. § 371 (e) (2) (3). The objections, which will be subsequently discussed in more detail, were mainly on the ground that the term "harmless" had long been judicially and administratively construed to mean "harmless and suitable for use in food" *under the in-*

tended conditions of their use and that petitioner's product could so qualify *when used within certain stated tolerances.*

Pharmacological studies conducted in the Food and Drug Administration's scientific laboratories had established that the colors in question were toxic when fed to laboratory animals, in that, while they produced no adverse physiological effects at 500 parts per million (0.05%) of the test animals' diets, they did produce such adverse effects at 1,000 ppm (0.1%) in the test diets. These studies and experiments formed the basis for the Deputy Commissioner's order of January 24, 1957, removing the coal tar colors in question from the harmless list.

After the objections were filed, a conflict arose between two Courts of Appeals over the construction of § 346 (b) as applied to the use of red coal tar colors. The 2nd Circuit, in *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 1956, 236 F.2d 866, sustained the power of the Secretary to delist those colors where laboratory tests showed that their addition to food might be injurious to health. The 5th Circuit, however, in *Florida Citrus Exchange* v. *Folsom*, 1957, 246 F.2d 850, held to the contrary and concluded that the Secretary could certify red coal tar colors for use in food on the basis of tolerances within which their use was harmless. Pending a resolution of this conflict by the Supreme Court, the delisting of the colors was stayed by administrative action, 22 F.R. 6612, August 17, 1957.

On December 15, 1958, the Supreme Court, in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 166, 167, reversed the holding of the 5th Circuit and in effect sustained that of the 2nd Circuit by holding that "where a coal-tar color is not harmless, it is not to be certified" and, therefore, that the Secretary "is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances."

On February 6, 1959, the Deputy Commissioner, without a hearing as provided for in 21 U.S.C.A. § 371 (e) (2) (3), published the final order delisting the colors in question. The order explained the failure to grant a hearing as follows:

> "The Supreme Court's (*Flemming* v. *Florida Citrus Exchange*, supra) decision having established the proper construction of the law, the objection of the Certified Color Industry Committee to the delisting of FD&C Yellow Nos. 1, 2, 3, and 4 is without substance, and no purpose could be served by holding a public hearing. The Department has no authority to certify colors that are themselves toxic, as is the case with FD&C Yellow Nos. 1, 2, 3, and 4, and the Department has no authority to establish a tolerance for such a color, as requested by the Industry Committee."

In this appeal, the petitioner requests that this court:

> "1. Review and set aside the Respondent's Order of February 6, 1959, insofar as it affects the production, sale and use of FD&C Yellows 3 and 4 for coloring edible fats, as being unsupported by substantial evidence of record adduced at a public hearing; and that the Court order the Respondent to hold a public hearing as required by the Federal Food, Drug, and Cosmetic Act; and
>
> 2. Direct that there be full consideration at such hearing of the effect of legislation enacted by Congress and proposed by Respondent since the decision in *Flemming* v. *Florida Citrus Exchange*, *supra*, in establishing the principle that coal tar colors may be approved under conditions appropriate to assure the safety of such use."

Petitioner's first contention is that the respondent's refusal to hold a public hearing invalidates the order. 21 U.S.C.A. §§ 371 (e) (2) (3) provide that:

> "(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any persons who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. * *
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. * * *"

Petitioner contends that the foregoing constitute an unconditional statutory requirement for a hearing upon the filing of objections and that they were wholly disregarded by the order deleting the colors from the harmless list, with the result that no chance was afforded petitioner and others to raise any objections that might be available or to question and refute the pharmacological evidence referred to in the Secretary's order.

Respondent counters by claiming that the grounds set forth in petitioner's objections were wholly insufficient

to warrant a hearing in that they sought the promulgation of regulations that were beyond the Department's authority.

Petitioner's "grounds for objection" were four in number. The first asserted that, "The colors affected by the order serve a useful and desirable purpose in coloring food and drugs," and that they had been so used for many years, principally with margarine and butter. Objection No. 2 alleged:

> "The evidence of potential injury from the use of FD&C Yellow Nos. 1, 2, 3 and 4 is inadequate to justify the order. Although there has not been any report of injury to humans from any of the four colors (as acknowledged by the Commissioner in a public statement of January 23, 1957), the order will prohibit their use in foods and internal drugs and cosmetics solely on the basis of pharmacological tests on animals in which the ingestion of massive doses of FD&C Yellow Nos. 1, 3 and 4 over long periods of time.
>
> (a) produced no adverse physiological effects at a concentration of 500 ppm (0.05%) of the animals' total diet; but
>
> (b) but produced some adverse physiological effects at a concentration of 1,000 ppm (0.1%) of the animals' total diet.
>
> The 'no-ham' level thus shown (500-1,000 ppm) is so far in excess of the level of actual use in the human diet that those results do not afford any basis for the order."

Objection No. 3 asserted that:

> "The reasonably anticipated uses of the four yellow colors do not justify any fear of injury from their use. * * *"

Objection No. 4:

"* * * urges that the Commissioner take action to prohibit such excessive concentrations, rather than to bar the proper and harmless use now being made of the colors."

It seems to us obvious, as it did to the respondent, that under the holding of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, supra, each of the objections set forth by the petitioner must be held inadequate to prevent the removal of the coal tar colors in question from the "harmless" list. Objection No. 1 merely asserts usefulness and desirability. While No. 2 alleges that the evidence of potential injury is inadequate to justify the order, it is based upon the contention that "the 'no-harm' level thus shown (500-1,000 ppm) is so far in excess of the level of actual use in the human diet that those results do not afford any basis for the order." No. 3 asserts that the reasonably anticipated uses do not justify fear of injury; and No. 4 suggests that the Commissioner do what the Supreme Court held he had no authority to do in *Flemming* v. *Florida Citrus Exchange*, supra. Therein, at page 163, the court stated:

"We are not persuaded by the respondents' argument, adopted by the Court of Appeals, that the words 'harmless' and 'poisonous' are relative words, referring not to the effect of a substance *in vacuo* but to its effect, taken in a particular way and in particular quantities, on an organic system. Of course this is so, but the question before us certainly does not depend on it. This is not a case like the examples put which remind us that pure water would be deleterious if taken at the rate of four gallons an hour or common table salt at several ounces. The color substances appear to have been administered at toxicologically significant levels; they played a relatively small part in

the diets of the test animals, generally less, and frequently much less, than 1%. Obviously if the color substances themselves are made an item of diet in the trifling percentages used on the test animals, their effect is poisonous. Congress may have intended 'harmless' in a relative sense, but we think it was in relation to such laboratory tests as the one the Secretary performed that Congress was speaking when it required that coal-tar colors be 'harmless'. *We do not believe that Congress required the Secretary first to attempt to analyze the uses being made of the colors in the market place, and then feed them experimentally only in the proportions in which they appeared in certain of the food products in which the colors were used. This appears to be the very procedure on which Congress turned its back in the 1938 Act.*" (Emphasis supplied.)

And at page 166:

"The Secretary contends that he is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances. We believe he is correct."

And finally at page 167:

"*The command of the statute is plain: where a coal-tar color is not harmless, it is not to be certified; if it is not certified, it is not to be used at all.* In this regard also, an approach in terms of the toxicity of the coloring ingredient, rather than of the food product as a whole was chosen by Congress. It evidently took the view that unless coal-tar colors were harmless, the considerations of the benefits of visual appeal that might be urged in favor of their use should not prevail, in the light of the considerations of the public health." (Emphasis supplied.)

We thus conclude that the four grounds set forth in the petitioner's objections to the order were legally insufficient and turn next to the question of whether a hearing must be held even though the prerequisite objections fail to state valid or legal grounds for the requested action.

It will be noted that 21 U.S.C.A. § 371 (e) (2) provides that objections may be filed "* * * stating the grounds therefor, and requesting a public hearing upon such objections * * *" and (3) "* * * the Secretary, after due notice, *shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections.*" (Emphasis supplied.) It is only after filing objections and "* * * stating the grounds therefor, and requesting a public hearing upon such objections * * *" that an interested party is entitled to a hearing. The hearing is solely for the purpose of receiving evidence "relevant and material to the issues raised by such objections". Certainly, then, the objections, in order to be effective and necessitate the hearing requested, must be legally adequate so that, if true, the order complained of could not prevail. The objections must raise issues". The issues must be material to the question involved; that is, the legality of the order attacked. They may not be frivolous or inconsequential. Where the objections stated and the issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to perform useless or unfruitful tasks. If it is perfectly clear that petitioner's appeal for a hearing contains nothing material and the objections stated do not abrogate the legality of the order attacked, no hearing is required by law.

Support for this conclusion is substantial. In *United States, et al.* v. *Storer Broadcasting Co.*, 1956, 351 U.S. 192, an application was made by the broadcasting company to the Federal Communications Commission for approval

of the company's acquisition of a sixth television station, despite the fact that the regulations allowed the ownership of only five. In holding that the Commission could deny the application without the hearing provided for under the controlling act, the court stated:

> "We agree with the contention of the Commission that a full hearing, such as is required by § 309 (b), n. 5, *supra*, would not be necessary on all such applications. As the Commission has promulgated its Rules after extensive administrative hearings, it is necessary for the accompanying papers to set forth reasons, sufficient if true, to justify a change or waiver of the Rules. We do not think Congress intended the Commission to waste time on applications that do not state a valid basis for a hearing. If any applicant is aggrieved by a refusal, the way for review is open." 351 U.S. at 205.

Similarly, in *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Assn.*, 1958, 356 U.S. 282, the court held a hearing unnecessary where regulations issued by a producer's association were invalid on their face under the Packers and Stockyards Act. In so doing, the court explained:

> "It is, of course, true that § 310 of the Act provides for a 'full hearing' on a complaint against a 'regulation' of a stockyard. That was also true of the Act involved in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192. But we observed in that case that we never presume that Congress intended an agency 'to waste time on applications that do not state a valid basis for a hearing.'" 356 U.S. at 287.

Finally, in *Sun Oil Co.* v. *Federal Power Commission*, 5 Cir., 1958, 256 F.2d 233, cert. denied 358 U.S. 872, the court stated:

"We come then to the final question of whether the failure of the Commission to give *Sun* notice and hold formal hearing before rescinding its rate schedule filings and cancelling its certificates of public convenience and necessity requires the setting aside of the Commission's orders. Although *Sun* urges to the contrary, we do not think there was any fact question involved and hence no evidence would have been material. If the question was more than a question of administrative policy, and we doubt that it was, it was a question of law. We do not believe there was a case of an adjudication which was required by the statute 'to be determined on the record after opportunity for an agency hearing' where notice is required by the Administrative Procedure Act. 5 U.S.C.A. § 1004. Nor do we think that the absence of notice has deprived *Sun* of due process as guaranteed by the Constitution. The only benefit that would have inured to *Sun* by notice and hearing would have been the privilege of making a legal argument before the Commission. We find no requirement in the Natural Gas Act for notice and hearing in such a situation." 256 F.2d at 240.

We hold that the respondent was correct and that no hearing need be held when the prerequisite objections are not supported by grounds legally sufficient to justify the relief sought.

Petitioner here also contends that the respondent's order is not supported by substantial evidence of record and hence may not be sustained. In so contending, petitioner overlooks the fact that the requirement that the order be based upon substantial evidence of record is found in 21 U.S.C.A. § 371 (e) (3). That section is not invoked until "objections" have been filed and, as we have heretofore indicated, no "objections" can be deemed to have been

filed when the grounds therefor raise no issues material to the legality of the disputed order.

Petitioner's second contention is that any hearing ordered should be required to include consideration of the legislative and administrative action which followed the Supreme Court's ruling in *Flemming* v. *Florida Citrus Exchange*, supra, as bearing upon the application of that decision to the certifiability of FD&C Yellow Nos. 3 and 4. As we have already determined that no hearing need be held, this point must obviously fail. Moreover, we find nothing contained in those subsequent events which alters our basic conclusion that petitioner is not entitled to a hearing.

The legislative and administrative history to which petitioner calls our attention is as follows: On November 10, 1955, the Secretary of Health, Education, and Welfare removed FD&C Red 32 which had been used in coloring green oranges from the list of certified coal tar colors because of its toxicity. This action led to the previously noted judicial appeals in the 2nd and 5th Circuits and eventually to the decision of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, supra, in December of 1958. Prior to this, however, on July 7, 1956, Congress, in response to the Secretary's order of November 10, 1955, amended 21 U.S.C.A. § 342 (c) under which the delisting had been required, to provide for temporary certification of Red 32 until March 4, 1959. The Supreme Court in its decision stated that this legislative action, because of its temporary character, did not make the issue of the validity of the delisting of Red 32 moot. Subsequent to this special legislation the color industry developed a substitute color for Red 32 known as Red 2 which was of a lower toxicity, but which was still not certifiable under the general, unamended provisions of 21 U.S.C.A. § 342 (c). On March 17, 1959, Congress extended the emergency legislation for the use of color additives for oranges to Sep-

tember 1, 1961, with the only change being that Red 2, rather than Red 32, was to be used under safe tolerances. Public Law 86-2, 86th Congress. Prior to the passage of this latter legislation, the Secretary, in letters of January 29, 1959, and February 16, 1959, to the hearing committees of the Senate and House respectively, approved the extension of the emergency acts and stated the Department's approval of previously proposed but unenacted legislation of general application embodying the use-under-safe-tolerances principle. Legislation to this effect was again introduced in the recently concluded session of Congress but was similarly not acted upon. H. R. 7624; S. 2197.

Petitioner points out that in *Helvering* v. *Hallock*, 1940, 309 U.S. 106, the Supreme Court reconsidered and abandoned its previous reading of a statutory provision and that it did so despite the government's argument that the *lack* of remedial Congressional action evidenced *approval* of the prior statutory construction so as to debar its judicial reexamination. Petitioner then argues:

> "Here, however, such reexamination not only is not barred but is strongly indicated in view of the positive legislation and direct administrative action already taken to avoid an unworkable interpretation of the coal tar color provisions of the Food, Drug, and Cosmetic Act,"

and that the meaning of the phrase "harmless and suitable for use in food" as it bears on petitioner's products should be construed in the light of these developments. Petitioner's argument is footless and can get nowhere. This court may not extend "judicial reexamination" to the Supreme Court's opinion in *Flemming* v. *Florida Citrus Exchange*, supra, on the basis of proposed Congressional legislation. *Wong Yang Sung* v. *McGrath*, 1950, 339 U. S. 33, 47. As to the specific legislation which granted

temporary relief from the Secretary's order removing Citrus Red No. 32 from the list of certified colors, the Supreme Court was aware of the earlier act to this effect passed in 1956 and found it without bearing on its decision. We reach the same conclusion in respect to the later legislation.

The order of which review is sought is affirmed.

A true Copy.

Attest:

Clerk, U. S. Court of Appeals, Eighth Circuit.

(Decree.)

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

September Term, 1959

No. 16225

DYESTUFFS AND CHEMICALS, INC., *Petitioner,*

vs.

ARTHUR S. FLEMMING, Secretary of Health, Education and Welfare, *Respondent.*

Petition for Review of Order of Secretary of Health, Education and Welfare.

This cause came on to be heard on the Petition for Review of the Final Order of the Secretary of Health, Education and Welfare entitled "In the Matter of amending the color-certification regulations with respect to FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4" entered February 6, 1959, and was argued by counsel.

On Consideration Whereof, It is now here Ordered, Adjudged and Decreed by this Court that the Final Order of February 6, 1959, in this cause, be, and it is hereby, affirmed.

And it is further Ordered by this Court that the Petition for review in this cause be, and the same is hereby, dismissed.

October 30, 1959.

FILE COPY

Office-Supreme Court, U.S.
FILED
FEB 24 1960
JAMES R. BROWNING, Clerk

No. 654

In the Supreme Court of the United States

OCTOBER TERM, 1959

DYESTUFFS & CHEMICALS, INC., PETITIONER

v.

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION, AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

J. LEE RANKIN,
Solicitor General,
MALCOLM R. WILKEY,
Assistant Attorney General,
BEATRICE ROSENBERG,
Attorney,
Department of Justice, Washington 25, D.C.

WILLIAM W. GOODRICH,
Assistant General Counsel for Food and Drugs,
ROBERT H. BICKER,
Attorney,
Department of Health, Education, and Welfare,
Washington 25, D.C.

INDEX

	Page
Opinion below	1
Jurisdiction	1
Question presented	1
Statutes involved	2
Statement	4
Argument	7
Conclusion	11

CITATIONS

Cases:

Certified Color Industry Comm. v. *Secretary of Health Education, and Welfare*, 236 F. 2d 866 — 9

City of Tacoma v. *Taxpayers*, 357 U.S. 320 — 11

Denver Union Stock Yard Co. v. *Producers Livestock Marketing Association*, 356 U.S. 282 — 7

Flemming v. *Florida Citrus Exchange*, 358 U.S. 153 — 1, 2, 5, 6, 7, 8, 9, 10

Florida Citrus Exchange v. *Folsom*, 246 F. 2d 850 — 5

Unemployment Commission v. *Aragon*, 329 U.S. 143 — 8

United States v. *Storer Broadcasting Co.* 351 U.S. 192 — 7

United States v. *Tucker Truck Lines*, 344 U.S. 33 — 8

Virginian Railway Co. v. *Mullens*, 271 U.S. 220 — 8

Statutes:

Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1049, 1055, as amended, 70 Stat. 919 (21 U.S.C. 301 *et seq.*):

Section 406(b) — 2, 4, 6

Section 701(e) — 2, 4, 6, 7, 9, 10

In the Supreme Court of the United States

OCTOBER TERM, 1959

No. 654

DYESTUFFS & CHEMICALS, INC., PETITIONER

v.

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION, AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App.) is reported at 271 F. 2d 281.

JURISDICTION

The judgment of the Court of Appeals was entered on Oct 30, 1959 (R. 107). The petition for a writ of certiorari was filed on January 22, 1960. The jurisdiction of this Court is invoked under 28 U.S.C. 1254 (1).

QUESTION PRESENTED

Before the decision of this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, petitioner had filed objections to removal by respondent of four toxic

coal-tar colors from the harmless list; these objections were all on grounds held invalid or irrelevant by this Court's decision. Some two months after the Court's ruling, the administrative order of removal, which had been stayed pending decision in the *Florida Citrus Exchange* case, was declared effective without a public hearing.

The question presented, for the first time in this Court, is whether it was error to promulgate the order at that time without a public hearing to allow petitioner to present further objections, although (a) no such further objections were ever filed, (b) none was specified or brought to the attention of the administrators before the order was promulgated, and (c) the statutory time for filing had long expired.

STATUTES INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1049, 1055, as amended, 70 Stat. 919 (21 U.S.C. 301, *et seq.*), provides in pertinent part as follows:

SECTION 406(b)

* * * * *

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents. [21 U.S.C. 346(b).]

SECTION 701(e)

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section * * * 406 (a) or (b), * * * 504, or 604, of this Act shall be begun by a proposal made (A) by

the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due

notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. * * * [21 U.S.C. 371(e).]

* * * * *

STATEMENT

On January 24, 1957, the Deputy Commissioner of Food and Drugs published a notice of the Food and Drug Administration's proposal to amend its regulations listing coal-tar colors which are "harmless and suitable for use in food" (Section 406(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346 (b)), 22 F.R. 478 (R. 1), by removing FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4, from the approved list for unrestricted use. This notice solicited the views and comments of interested parties.

After consideration of the comments received, including those of the Certified Color Industry Committee (R. 35–39) of which petitioner is a member, the Commissioner, on May 4, 1957, published an Order removing the colors in question from the approved food, drug, and cosmetic color list, 22 F.R. 3173 (R. 40), because they "are not harmless and suitable for use within the meaning of" the color certification provisions of the Act. This Order was to become effective 90 days after publication, unless stayed by the filing of proper objections (Section 701(e), 21 U.S.C. 371(e)).

On May 27, 1957, within the 30 days allowed by law, the Certified Color Industry Committee filed objections to the Order, stating the grounds therefor, as required by the statute (Section 701(e)(2), 21 U.S.C. 371(e)

(2)), and requesting a public hearing (R. 41–45). The grounds stated were as follows:

> 1. The colors in question are useful in the coloring of food and drugs (R. 42).
>
> 2. Pharmacological tests show that the level at which these colors produce adverse physiological effects is far in excess of their actual level of use in the human diet. There is therefore no adequate evidence of potential injury (R. 43).[1]
>
> 3. The reasonably anticipated uses of the four colors do not justify any fear of injury from their use (R. 43).
>
> 4. Rather than delist these colors completely, the Commissioner should establish tolerances for their use in oleomargarine and butter (R. 44–45).

In July 1957, after the objections had been filed, the Court of Appeals for the Fifth Circuit decided *Florida Citrus Exchange* v. *Folsom*, 246 F. 2d 850. Pending certiorari to review that judgment, delisting of the four yellow colors was stayed by administrative action, 22 F.R. 6613, August 17, 1957 (R. 46). On December 15, 1958, this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, reversed the judgment of the Fifth Circuit. It held that, "where a coal-tar color is not harmless, it is not to be certified" (p. 167), and that the Secretary "is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances" (p. 166). Petitioner now ad-

[1] The pharmacological studies referred to in the objections were conducted in the Food and Drug Administration's scientific laboratories.

mits (Pet. 6) that "the only factual issue which petitioner had considered or contested in its 1957 objections became irrelevant" when *Florida Citrus* was decided.

On February 6, 1959, the Deputy Commissioner of Food and Drugs published the "Final Order" delisting these colors, 24 F.R. 883 (R. 47). The Order recited the history of the delisting proceeding, and explained that, since under this Court's decision in *Florida Citrus* the Department of Health, Education and Welfare could not establish a tolerance for a toxic color, no purpose could be served by holding a public hearing on objections seeking the promulgation of regulations that were beyond the Department's authority.

On May 6, 1959, the petitioner filed in the Court of Appeals for the Eighth Circuit a petition for review of the Food and Drug Administration's Order. As grounds, that petition stated, in paragraph 3 (R. 49):

> Under Section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)), said Secretary is required, upon request, to hold a public hearing upon the proposed issuance, amendment or repeal of any regulation under Section 406(b) and other sections of the Act. No public hearing has been held upon the proposed deletion of FD&C Yellows 3 and 4 from the list of colors certified for use in food color although public hearing was duly requested, and the Secretary, by his order of February 6, 1959, has refused to hold the requested hearing.

The Court of Appeals held that the statute does not unconditionally require a hearing, upon the mere filing

of objections, regardless of the validity of the filed objections. It said that where "it is perfectly clear that petitioner's appeal for a hearing contains nothing material and the objections stated do not abrogate the legality of the Order attacked, no hearing is required by law" (Pet. App. 9a). Finding that under *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, "each of the objections set forth by the petitioner must be held inadequate to prevent the removal of the coal tar colors in question from the 'harmless' list" (Pet. App. 7a), the Court of Appeals affirmed the Department's order and dismissed the petition for review (R. 107, Pet. App. 14a–15a).

ARGUMENT

This petition for certiorari has abandoned the only issue raised in the petition for review filed in the Court of Appeals (R. 48–50). There, petitioner urged that, under Section 701(e) of the Federal Food, Drug and Cosmetic Act, the Secretary was required automatically to hold a hearing on the basis of the objections and request previously filed by petitioner. See *supra*, p. 6. Petitioner now admits (Pet. 6) that its 1957 objections are irrelevant under the ruling of this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153. And, it now concedes (Pet. 7) that under *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Association*, 356 U.S. 282, and *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192 (cases it sought to distinguish below), a public hearing need not be held when the grounds upon which the hearing

is requested are, as a matter of law, not relevant or material to the proper issues.

Petitioner now urges in this Court[2] that, nevertheless, the Order should not have been promulgated without a public hearing in order to give it an opportunity to present *new* objections to the "new" Order. One short answer is that, in the almost two-month period between this Court's decision in *Florida Citrus* and the promulgation of this Order, no attempt was made by petitioner to file such new objections.[3] Moreover, the Order of February 6, 1959, under review here, was

[2] After bringing and arguing its case on the theory that it was entitled to a hearing on the basis of its request, petitioner should not be permitted to change to a wholly new and inconsistent position. Cf. *Virginian Railway Co.* v. *Mullens*, 271 U.S. 220; *United States* v. *Tucker Truck Lines*, 344 U.S. 33; and *Unemployment Commission* v. *Aragon*, 329 U.S. 143, 155.

[3] At no time between December 15, 1958 and February 6, 1959, did the petitioner or the Industry Committee, of which it is a member, express a desire to file new objections, though a draft of the February 6 order was mailed in advance to the Industry Committee in late January, 1959. There is thus no substance to the claim that respondent's activities were so paced that petitioner had no opportunity to file new and pertinent objections (Pet. 8).

While petitioner asserts that its petition for review in the court below questioned the validity of the Order on the ground that it had not been permitted "to file relevant objections", and that it requested the Court of Appeals to direct the Department to consider objections it was prepared to make (Pet. 4), such objections were not in fact incorporated in the petition for review. Indications of the contemplated objections are found in the Court of Appeals opinion (Pet. App. 11a–14a). These were that the Order was not supported by substantial evidence and that the Department should be required to reconsider the *Florida Citrus* opinion in the light of subsequent administrative and legislative developments. These objections presented no basis for a hearing, as the Court of Appeals has held.

not a "new" order. The May 4, 1957 Order, to which petitioner filed timely objections, was stayed from August 7, 1957, until the February 6, 1959 Order. All the "new" order did was to act on the petitioner's objections in the light of this Court's December 1958 opinion in *Florida Citrus*. The original "Proposal" (R. 1), the "Order Acting on the Proposal" (R. 40), the "Order Staying the Effectiveness of Amendment" (R. 46), and the "Final Order" (R. 47), are all part of the same delisting proceeding. Petitioner's statutory time (of 30 days) to file objections ran from the date of the "Order Acting on the Proposal", *i.e.*, May 4, 1957. (See Section 701(e)(2), *supra*, p. 3.) The fact that petitioner did not discover that the objections which it filed at that time were legally insufficient until the decision of this Court in *Florida Citrus* did not give it the right to file additional objections. Late discovery of the governing law is no basis for filing new objections after the statutory period for objections has expired.[1]

If petitioner believes that it still has reasonable grounds for establishing that Yellows 3 and 4 are "harmless and suitable for use", as this Court has interpreted that language in *Florida Citrus*, a remedy is available. It may petition the Secretary for the relisting of these colors and, upon the showing of

[1] The Second Circuit had issued its opinion, upholding the respondent's order relating to Red 32, on August 10, 1956. *Certified Color Industry Comm.* v. *Secretary of Health, Education and Welfare*, 236 F. 2d 866. The Fifth Circuit's opinion in the Red 32 case (reversed by this Court) was not issued until July 1957, after petitioner had filed its objections to the proposed order in this case (on May 27, 1957). *Supra*, pp. 4–5.

reasonable grounds, a new administrative proceeding, which may include both hearing and judicial review, must be held (Section 701(e), 21 U.S.C. 371(e)). But the right to challenge the delisting order of May 4, 1957, was lost when no legally valid objections were filed within the 30 days allowed by Congress in Section 701(e)(2).

To initiate a new proceeding for relisting Yellows 3 and 4, petitioner would have to show that the colors themselves are non-toxic. Nowhere in the petition for review, the brief below, or in the petition for certiorari is there any indication that petitioner has any evidence to refute the scientific studies on which the Secretary's Order was based. These studies plainly showed that the colors are not "harmless". Unless new evidence is developed, the colors cannot be retained on the "harmless" list, under the present statute.

The reference (Pet. 9) to the recent order of the Commissioner of Food and Drugs issued on January 8, 1960, 25 F.R. 143—as indicating that the Commissioner and the court below have distorted and misapplied this Court's opinion in *Florida Citrus Exchange, supra,* as dispensing with hearings—is without justification. That order did not purport to remove any coal-tar colors from any of the relevant lists; it merely provided that all "certificates" which had been issued for batches of the colors, including Yellows 3 and 4, *prior* to the effective date of their removal from the approved list, would cease to be effective on April 6, 1960. The objections referred to in the portion of the order quoted by the petitioner (Pet. 9–10) were filed by petitioner in an entirely different

proceeding in an attempt collaterally to attack the factual basis for this delisting order. Since the delisting order has been affirmed, it is not subject to attack except in the present proceeding (*City of Tacoma* v. *Taxpayers*, 357 U.S. 320, 324), or until it is set aside in a new proceeding as suggested above; and the Commissioner properly so ruled in his recent order. The portion of that order quoted by petitioner does not indicate that the respondent will refuse to hold a hearing when adequate grounds are stated in properly filed objections; it indicates only that the respondent will not hold hearings on legally invalid "objections" (such as belated efforts to attack a delisting order collaterally).

CONCLUSION

For the foregoing reasons, it is submitted that this petition for a writ of certiorari should be denied.

Respectfully submitted.

J. LEE RANKIN,
Solicitor General.
MALCOLM R. WILKEY,
Assistant Attorney General.
BEATRICE ROSENBERG,
Attorney.

WILLIAM W. GOODRICH,
Assistant General Counsel
for Food and Drugs,
ROBERT H. BECKER,
Attorney,
Department of Health,
Education, and Welfare.

FEBRUARY 1960.

U. S. GOVERNMENT PRINTING OFFICE 1960